

DECLARATION OF CONFORMITY		
(check all conformity route(s) based on EU MDD Article 17 requirements for the device class and specifics)		
Annex II (4) <input type="checkbox"/>	Annex V <input type="checkbox"/>	Annex III <input type="checkbox"/>
Annex II (3) <input checked="" type="checkbox"/>	Annex VI <input type="checkbox"/>	Annex IV <input type="checkbox"/>
		Annex VII <input type="checkbox"/>

Technical File Number and Version: DU-VC-006 Version 8 Device Trade Name: DAILIES TOTAL1 (delefilcon A) Soft Contact Lens Supersedes (Date): 04-Mar-2020	
Manufacturer: Alcon Laboratories Inc Address: 6201 South Freeway, Fort Worth, TX 76134 USA Manufacturing Site(s): CIBA VISION GmbH Industriering 1, 83068 Grosswallstadt, Germany Alcon Research, LLC 11440 Johns Creek Parkway, Duluth, GA 30097	Authorized Representative in the European Community* Alcon Laboratories Belgium Address: Lichterveld 3 2870 Puurs-Sint-Amands, Belgium *Previously Alcon Laboratories (UK) Ltd. Frimley Business Park, Frimley, Camberley Surrey, GU16 7SR, United Kingdom Alcon Laboratories Belgium BVBA** Rijksweg 14 2870 Puurs, Belgium

Device (Trade Name)	GMDN Code & Term	Catalogue Number	Class
DAILIES TOTAL1 (delefilcon A) DAILIES TOTAL1 multifocal (delefilcon A) DAILIES TOTAL1 PRO (delefilcon A)** DAILIES TOTAL1 PRO multifocal (delefilcon A)** DAILIES TOTAL1 for ASTIGMATISM (delefilcon A)**	47841 Soft corrective contact lens, daily disposable	NA	Ila

<p>The device(s) covered by this declaration are in conformity with the European Medical Devices Directive 93/42/EEC as well as other relevant Union legislation that make provisions for the issuing of a declaration of conformity as listed.</p> <p>Alcon Laboratories, Incorporated hereby declares under its sole responsibility that the listed device(s) and Quality Systems conform(s) to</p> <p style="text-align: center;">EU MDD 93/42/EEC as amended</p> <p>This Declaration is applicable to all products listed and released after the Date of Issuance of this Declaration of Conformity, and until a revised Declaration of Conformity is issued.</p> <p>Notified Body Information: Applicable <input checked="" type="checkbox"/> Not Applicable <input type="checkbox"/></p> <p>Conformity Assessment: Certificate Number(s): G1 020896 0388</p> <p>Notified Body: TÜV SÜD Product Service GmbH **Previously BSI, Kitepark Court, Davy Avenue, Kitepark Hill, Milton Keynes MK5 8PP UK with identification number D086. identification number: 0123</p> <p>Address: Rüdigerstraße 65 D-80335 München, Germany</p>

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Regulations, Directives and Standards Applied: EN ISO 13485 as currently published		
Place of Issue Alcon Laboratories Incorporated Fort Worth, TX USA	Date of Issue: <i>05-19-20</i>	Lakota Sherri <small>Digitally signed by Lakota Sherri DN: cn=Lakota Sherri, o=Alcon, ou=Alcon, email=Lakota.Sherri@alcon.com, c=US</small> Name/Title/Function/Date: Sherri Lakota/VP GRA VC & DEOH

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